

REMARKS

Claims 1 and 10 are pending. The claims have been amended to more particularly point out and distinctly claim the subject matter Applicant regards as the invention. Support for the claimed invention is found in the application as originally filed. No new matter has been added.

At ¶'s 2-3 of the Office Action, claims 1 and 10 stand rejected under 35 USC 103(a) as being obvious over WO 97/16360 in view of USPN 3,709,410 (the '410 patent). For convenience, the Examiner and Applicant refer to USPN 6,112,950 (the '950 patent) which is based on WO 97/16360. Applicant respectfully traverses the rejections.

The '950 patent discloses an metered dose inhaler having, among other components, a metering chamber 2 and a valve plunger 10. The plunger 10 corresponds to the valve stem of the present invention. The valve plunger includes a top element 10a and a bottom element 10b. (See col. 3, lines 3-23 and Figs. 1 and 2). The valve plunger 10 is molded from a mixture of acetal resin, PTFE and silicone to lower friction with the valve gasket. (See col. 2, lines 22-38). The '950 patent does not suggest or teach making any components (other than the plunger) using a fluorinated polymer, such as PTFE. The '950 patent is also silent regarding drug deposition on any components of the MDI, such as the metering chamber.

The '410 patent discloses a *non-metering* aerosol valve having a uni-directional, pressure-actuated, expanding slot valve body for improved rapid filling ability. (See Abstract and Col. 2, lines 3-65). The '410 patent also discloses that the valve body 20 may be made of teflon. (Col. 3, lines 50-51). The valve body 20 defines the cup portion 20 and the tubular section 26. (See Col. 3, lines 52-54 and Figs. 2 and 3). Upon actuation and filling, aerosol product flows through the valve interior defined by the valve body 20. (Col. 3, lines 43-49 and col. 4, lines 28).

However, because the aerosol valve disclosed in the '410 patent is *non-metering*, none of the aerosol product resides within the valve for any appreciable length of time. In the metering valve of the presently claimed invention, upon actuation, pharmaceutical product from the canister is

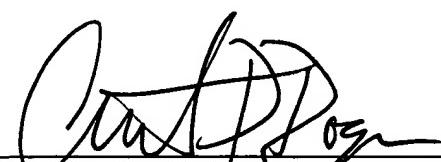
metered into the metering chamber 2 where it resides until the next actuation. Particularly in HFA formulations, drug particles suspended in the HFA propellant deposit on the walls of the metering chamber. (See Page 2, lines 25-30). The fluorinated ethylene propylene, copolymer of a polytetrafluoroethylene and combinations thereof materials used to make the walls of the metering chamber significantly reduce or eliminate such drug deposition.

The instantly claimed invention is patentably nonobvious over the '950 and '410 patents because, *inter alia*, the references fail to teach or suggest using the fluorinated ethylene propylene, copolymer of a polytetrafluoroethylene or combinations thereof materials. The references also fail to motivate the ordinary artisan to incorporate the non-metering valve body 20 of the '410 patent into the metering valve of the '950 patent. The '410 patent simply fails to teach or suggest any reason for substituting its non-metering body 20 for the valve body 1 of the metering valve in the '950 patent. Reconsideration and withdrawal of the rejection is respectfully requested.

For the above reasons, Applicants respectfully traverse the rejections and objections set forth in the outstanding Office Action and request that they be withdrawn. Applicants respectfully contend that the application is in condition for allowance and requests the same. The Examiner is invited to contact the undersigned should there be any questions or concerns.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CHANGES MADE TO CLAIMS

1. (Twice Amended) A metering valve for dispensing a pharmaceutical product, comprising:

a valve body[.] constructed from a material selected from the group consisting of a fluorinated ethylene propylene, a copolymer of a polytetrafluoroethylene and combinations thereof, wherein the valve body defines [defining] a metering chamber, [constructed from a fluorinated polymer, and]

one or more seals,

a valve stem, and

a spring.

Kindly cancel claims 2 and 6-9 without prejudice or disclaimer thereof.

10. (Amended) A metered dose inhaler comprising:  
an aerosol container containing a drug and a hydrofluoroalkane propellant,

a valve body constructed from a material selected from the group consisting of a fluorinated ethylene propylene, a copolymer of a polytetrafluoroethylene and combinations thereof, wherein the valve body defines a metering chamber,

[a metering chamber constructed from a fluorinated polymer, and]

one or more seals,

a valve stem, and

a spring.